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10/674,914	09/30/2003	Bevil J. Hogg	5236-000452	8982

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HARNESS, DICKEY, & PIERCE, P.L.C  
7700 BONHOMME, STE 400  
ST. LOUIS, MO 63105

EXAMINER
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NGUYEN, HUONG Q

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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12/13/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/674,914

Applicant(s)

HOGG ET AL.

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-17,38-40,51 and 52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-17,38-40,51 and 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

1. This Office Action is responsive to the RCE filed 10/17/2007. Claims 1, 38, and 52 are amended. Claims 7, 18-17, 41-50, and 53 are cancelled, overcoming the previous claim objection. **Claims 1-6, 8-17, 38-40, and 51-52** remain pending.

#### ***Drawings***

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: “57” in ¶0019 and “97” in ¶0021 of p.7 of the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

#### ***Claim Objections***

3. **Claims 51-52** are objected to because of the following informalities: Claim 51 recites dependency upon cancelled claim 50. It is therefore believed that Claim 51 meant to be cancelled as well and will be treated as such in the following rejection. Applicant is requested to review said claim and determine its appropriate status and/or dependency.

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Claim 52 should recite "a control system...for controlling THE elongate medical device that further includes at least one magnet." It is noted that the recitation of the magnet is already previously introduced in the claim. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. **Claim 1-6, 8-9, 11-12, 17, 38-40, and 52** are rejected under 35 U.S.C. 102(e) as being anticipated by Viswanathan (US Pub No. 20040068173).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

6. In regards to **Claim 1**, Viswanathan discloses a medical navigation system for controlling the distal end of an elongate flexible medical device in a subject's body, the system comprising:

an elongate flexible medical device having on its distal end one or more magnetically responsive elements that respond to an externally applied magnetic field to change the direction of the distal end of the medical device (§0048), and an electronic identification device that includes information on the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements, i.e. one magnet and spacing therebetween, and identification information that provides for elongate flexible medical device identification (§0042, 0047-0048, 0094);

a navigation device 58 configured to create a magnetic field used to steer the elongate flexible medical device, and to determine, as a function of the physical and geometric properties, actuation control variables for an applied actuation consisting essentially of an external magnetic field, where the navigation device determines and applies an appropriate magnetic field direction for actuating the distal end of an elongate flexible medical device and thereby changing its orientation (§0005, 0008, 0048, 0094, 0103);

an electronic interface for selectively operating for selectively controlling the orientation of the distal end of the elongate flexible medical device, the electronic interface comprising a processor 64 and inherently including at least one software program that enables navigation control only in the presence of the electronic identification device, wherein said electronic identification device is necessary to obtain the correct values, wherein the interface provides actuation instructions to the navigation device for controlling the distal end of the device, which instructions take into account the physical and geometric properties of the elongate medical device, including the number of magnetically responsive elements and spacing therebetween, i.e. one magnet

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(¶0048) that were obtained from the electronic identification device (¶0005, 0008, 0048, 0094).

7. In regards to **Claim 2**, Viswanathan discloses the electronic identification device includes a memory, and wherein the interface includes a reader for reading the memory (¶0042, 0047-0048, 0094).

8. In regards to **Claim 3**, Viswanathan discloses the electronic identification device includes a memory unit and a processing unit that communicates with the interface for transferring information.

9. In regard to **Claims 4-5 and 8-9**, Viswanathan discloses the memory contains unique identifying information about the type of device, and wherein the interface includes a database of the unique identifying information of the type of devices with which the interface is intended to operate (¶0042, 0047-0048, 0094).

10. In regard to **Claims 6 and 12**, Viswanathan discloses the electronic identification device is an integrated circuit that is connected to the interface.

11. In regards to **Claim 11**, Viswanathan discloses the interface inherently includes a plurality of programs, each adapted for use with a different type of elongate flexible medical device, each program operating only when an electronic identification device for

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the particular type of elongate flexible medical device is present, wherein said electronic identification device is necessary to obtain the correct values.

12. In regards to **Claim 17**, Viswanathan discloses the at least one software program controls navigation by employing a computational model of flexible device physics (§0048, 0103).

13. In regards to **Claim 38**, Viswanathan discloses a medical navigation system for controlling the distal end of an elongate medical device in the body of the patient comprising:

an elongate flexible medical device (§0048);

a memory device provided with the flexible medical device including stored information such as lookup tables that includes information on the physical and geometric properties including one or more cross sectional areas of the elongate device and an elastic property of the elongate medical device that are relevant to navigational control of the device (§0042, 0047-0048, 0094);

a control system 58 for controlling the position and/or orientation of the distal end of the elongate medical device, where the one or more cross-sectional areas of the device and the elastic property of the device are used in navigational control algorithms for guiding the device, i.e. the stiffness or elasticity of the device is required to determine the amount of applied magnetic field to reach the desired target (§0094);

an interface for accepting inputs from the user to cause the control system to selectively change the position and/or orientation of the elongate medical device; the

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interface sending instructions to the control system dependent in part upon the medical device's physical and geometric property information, including one or more cross-sectional areas of the device, and the elastic property of the device obtained from the memory device, wherein the physical and geometric properties of the device are used in navigational control algorithms for guiding the device (§0005, 0008, 0048, 0094).

14. In regards to **Claim 39**, Viswanathan discloses the interface incorporates a software program that controls navigation by employing a computational model of flexible device physics (§0048, 0103).

15. In regards to **Claim 40**, Viswanathan discloses the memory device includes storing unique device identification information for the elongate flexible medical device, and wherein the interface includes a database of unique device identification information and corresponding device properties, and wherein the instructions sent to the control system take into account the device properties determined from the database (§0047, 0094).

16. In regards to **Claim 52**, Viswanathan discloses a medical navigation system for controlling the distal end of an elongate medical device in the body of the patient comprising:

an elongate flexible medical device including at least one magnet (§0048);

a memory device provided with the flexible medical device including stored information such as lookup tables that includes information on the physical and



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geometric properties of the elongate medical device that are relevant to navigational control of the device (§0042, 0047-0048, 0094);

a control system 58 for controlling the position and/or orientation of the distal end of the elongate medical device; wherein the control system is a magnetic navigation system for controlling the elongate medical device that includes at least one magnet, and said information includes physical properties of the elongate medical device including at least a magnet dimension or a magnet type, i.e. a single permanent magnet (§0048);

an interface for accepting inputs from the user to cause the control system to selectively change the position and/or orientation of the elongate medical device; the interface sending instructions to the control system dependent in part upon the medical device's physical and geometric property information, including the magnet dimension or magnet type obtained from the memory device, wherein the physical and geometric properties of the device are used in navigational control algorithms for guiding the device (§0005, 0008, 0048).

### ***Claim Rejections - 35 USC § 103***

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. **Claims 13-16** are rejected under 35 U.S.C. 103(a) as being obvious over Viswanathan in view of Osadchy et al (US Pat No. 6266551).

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The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

19. Viswanathan discloses the invention above but does not disclose preventing reuse of the elongate flexible medical device by adding or deleting information on the memory of the electronic identification device or when an elapsed time has exceeded a pre-defined limit. Osadchy et al disclose an analogous elongate flexible medical device comprising an interface 36 operating on an electronic identification device 90 to prevent reuse of the elongate flexible medical device (Col.18: 46-55) wherein the interface adds to or deletes information stored on the memory to prevent reuse of the device (Col.18: 9-55), and wherein the interface 36 also tracks elapsed time of use of the identified elongate

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flexible medical device 20 and invalidates use of the identified elongate flexible medical device when the elapsed time exceeds a pre-defined limit (Col.17: 55-65; Col.18: 46-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Viswanathan such that the electronic identification device prevents reuse in the manner above as taught by Osadchy et al to effectively provide safety features for the device.

20. **Claim 10** is rejected under 35 U.S.C. 103(a) as being obvious over Viswanathan in view of Burnside et al (US Pat No. 6237604).

21. The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

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22. Viswanathan discloses the electronic identification device above that transmits a signal to the interface above but do not disclose said device is RF circuit. Burnside et al teach the use of an RF circuit to effectively transmit a signal (abst). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the circuit of Viswanathan a RF circuit as taught by Burn

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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HQN

12/4/2007

A handwritten signature in cursive script, appearing to read "zen".A handwritten signature in cursive script, appearing to read "M. H. Smith".